

REMARKS

Applicants' representatives thank the Examiner for the interview of July 15, 2005 and for a telephone conversation on August 2, 2005. The amendments and remarks herein are made in accordance with our conversations. Additionally, during the interview, the Examiner asked Applicants to review the Image File Wrapper of this application in PAIR for accuracy. Applicants have done so and provide the results of their analysis herewith. See, "Image File Wrapper Evaluation for Application No. 09/880,748 as of August 3, 2005" with Attachments 1-3, submitted herewith.

Status of the Claims

Upon entry of these remarks, claims 97-100, 119-127 and 130-152 will be pending in this application.

Amendments to the Specification

A marked up version of the specification showing changes compared to the substitute specification filed in marked up form on December 14, 2004 and in clean form on January 18, 2005 is submitted herewith. The only changes in the Substitute Specification submitted herewith compared to the immediate prior version of the Specification can be found in Table 1. In Applicants' Substitute Specification filed December 14, 2004, the column in Table 1 entitled "AAs of VL" was inadvertently duplicated as a column entitled "AAs of L." Amendments were made to the first column entitled AAs of VL, but not to the second, duplicate "AAs of L" column. As is clear from the record, the amended column was intended. In the Substitute Specification filed herewith, Applicants have removed the second, duplicate "AAs of L" column. Applicants have filed a complete Substitute Specification in both clean and marked-up versions in accordance with the Examiner's request.

Amendments to the Claims

Claims 144 and 145 have been amended to replace the term "ATCC™" with the phrase "American Type Culture Collection". Applicants submit no new matter has

been added by way of these amendments and respectfully request entry of these amendments.

Double Patenting Rejections

Rejection under 37 CFR § 1.78(b)

The Examiner held that claims 97-100 and 119-152 of the present application are in conflict with claims 3, 4, 5, 6, 7, 17-19, 20, 21, 33 and 35 of U.S. Application No. 10/293,418 (hereafter the '418 application). Specifically, using form paragraph 8.29 from MPEP § 822, the Examiner stated that

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application *may* be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. (emphasis added, *See Office Action mailed May 4, 2005, paragraph bridging pages 3-4*).

MPEP § 822 also indicates that form paragraph 8.29 "...should be used when the conflicting claims are identical or conceded by applicant to be not patentably distinct." Applicants submit that at least insofar as claims 3, 4, 5, 6, 7, 17-19, 20 and 21 of the '418 application are concerned, the claims are not identical, nor have they been conceded by Applicant to be not patentably distinct. Applicants also note that under 37 CFR § 1.78(b), the Examiner is not obligated to require elimination of conflicting claims from all but one application. Rather, the Examiner has some discretionary power in this matter.

Furthermore, in accordance with a telephone conversation with Examiner Duffy on August 2, 2005, Applicants note: (1) that the '418 application has not yet been substantively examined and that the claims currently on file in the '418 application are identical to those originally filed in the present application; and (2) that the claims in the present application were restricted from each other on several bases, including restriction between individual SEQ ID NOS from the set of SEQ ID NOS:1-2128 (see Requirement for Restriction mailed May 7, 2003). Applicants have not yet received a Restriction Requirement in the '418 application, but assure the Patent Office that Applicants do not intend to pursue claims to the same invention as is claimed herein in the '418

application. Applicants respectfully request that the present rejection under 37 CFR § 1.78(b) be reconsidered and withdrawn.

Statutory Double Patenting and Double Patenting Under The Judicially Created Doctrine Of Obvious-Type Double Patenting

Claims 97-100 and 119-152 have been provisionally rejected for either statutory double patenting or double patenting under the judicially created doctrine of obvious-type double patenting over claims 33 and 35 of copending U.S. Application No. 10/293,418. The Examiner provisionally rejected claims 144 and 145 under the statutory type double patenting under 35 U.S.C. § 101 (see second full paragraph on page 5 of the Office Action mailed September 14, 2004) and claims 97-101, 119-143 and 146-152 under the judicially created doctrine of obvious-type double patenting (page 4 of the Office Action mailed May 4, 2005).

In response, Applicants direct the Examiner's attention to MPEP § 804, I.B. at page 800-19, which indicates that provisional double patenting rejections should be made in both of two copending applications as long as there are conflicting claims. It also instructs that,

[i]f the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent.

Applicants respectfully request that these provisional double patenting rejections be withdrawn from the present application if the remaining objections and rejections in the present application are overcome or obviated by the present Response.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 144 and 145 were rejected under 35 U.S.C. § 112, as allegedly being indefinite, for using the term "ATCC™." In a telephone conversation with Examiner Duffy on August 2, 2005, the Examiner indicated this rejection could be overcome by reciting "American Type Culture Collection" in the claims in lieu of "ATCC™".

Applicants have amended claims 144-145 in accordance with the Examiner's suggestion. Accordingly, Applicants respectfully request that this rejection of claims 144 and 145 under 35 U.S.C. § 112, second paragraph be reconsidered and withdrawn.

Objections to the Specification under 35 U.S.C. § 132(a)

In Applicants' Response submitted December 14, 2004, Applicants amended Table 1 to correct an obvious error, which is permissible "where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction." See, MPEP § 2163.07.

Specifically, the delineation of the amino acid residues that define the light chain variable region (VL region) of certain scFvs in column three of Table 1 were incorrect in the specification as originally filed. Applicants asserted the amendments were corrections of obvious errors. In support of this statement, Applicants submitted the Declaration Of Rodger Smith Under 37 C.F.R. § 1.132 (hereinafter the "Smith I Declaration"), to substantiate the fact that one of ordinary skill in the art would easily have been able to recognize and correct the errors in the third column of Table 1 entitled "AAs of VL". Dr. Smith stated in paragraph 9 of the Smith I Declaration that "[t]he beginning of the VL region in an scFv may be easily delineated by 1) determining whether the scFv contains a kappa or a lambda variable domain and then 2) calculating the first amino acid sequence based on a standard numbering system for immunoglobulin variable regions that was established by Elvin A. Kabat and Tai Te Wu in the 1970's that is widely used by immunologists even today."

The Examiner was not persuaded by the Smith I Declaration and indicated that the proposed amendments did not meet the standard for corrections of obvious errors as set forth in MPEP § 2163.07. In particular, the Examiner raised concerns regarding the ability of one of skill in the art to determine if a VL domain is a kappa ($V\kappa$) or a lambda ($V\lambda$) VL domain based on alignments to known VL sequences and about the Kabat-Wu numbering system. The Examiner rejected the amendments as new matter under 35 U.S.C. § 132(a).

Applicants met with the Examiner on July 15, 2005 to discuss this rejection and submit herewith a second Declaration of Rodger Smith Under 37 C.F.R. § 1.132 (hereinafter the "Smith II Declaration"), to clarify certain points made in the Smith I

Declaration. Applicants believe that the Smith II Declaration addresses the Examiner's concerns and makes it clear that the requested amendments are obvious errors to those of ordinary skill in the art. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully request that the above remarks be made of record in the file history of the instant application. Applicants respectfully submit that the present application is now in condition for allowance. A Notice of Allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below.

If there are any fees due in connection with the filing of this paper, not accounted for on the Fee Transmittal sheet submitted herewith, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 CFR § 1.136 that is not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: August 4, 2005

Respectfully submitted,

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